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ANDREA Q. RYAN				
SANOFI-AVENTIS U.S. LLC				
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BRIDGEWATER, NJ 08807				
EXAMINER				
STEADMAN, DAVID J				
ART UNIT		PAPER NUMBER		
1656				
NOTIFICATION DATE		DELIVERY MODE		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USPatent.E-Filing@sanofi-aventis.com
andrea.ryan@sanofi-aventis.com

Office Action Summary**Application No.**

10/076,632

Applicant(s)

HABERMANN, PAUL

Examiner

David J. Steadman

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 April 2010 and 21 June 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-24, 30-33 and 35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-24, 30-33 and 35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Status of the Application

- [1] Claims 22-24, 30-33, and 35 are pending in the application.
- [2] Applicant's amendments to the claims, filed on 4/7/10 and 6/21/10, are acknowledged. The claim amendment filed on 6/21/10 replaces all prior versions and listings of the claims.
- [3] Applicant's remarks filed on 4/7/10 and 6/21/10 in response to the non-final Office action mailed on 1/15/10 and the Office communication mailed on 6/14/10, respectively, have been fully considered and are deemed to be persuasive to overcome at least one of the rejections and/or objections previously applied. It is noted that the remarks filed on 6/21/10 appear to be cumulative to the remarks filed on 4/7/10. As such, only the remarks filed on 6/21/10 will be addressed in this Office action.
- [4] The text of those sections of Title 35 U.S. Code not included in the instant action can be found in a prior Office action.

Claim Objections

- [5] The objection to claim 31 in the recitation of "B_n is 1-15 codons, when n is an integer from 1 to 15, or a chemical bond, when n=0;" is maintained. The objection was fully explained in the prior Office action. See [6] beginning at p. 2 of the Office action mailed on 1/15/10. Although the instant remarks assert the objection is obviated by adopting the examiner's suggested language, no such amendment has been made to claim 31. In order to improve claim form and consistency, it is suggested that the noted

phrase be amended to recite, *e.g.*, "B_n is a chemical bond or a codon, wherein n=0-15 and B_n is a chemical bond when n=0 or B_n is 1-15 codons when n=1-15, respectively;".

[6] The objection to claims 22-24 and 30 to in the recitation of "Asm is a chemical bond, when m=0, or 1-10 codons, when m is an integer from 1 to 10;" is withdrawn in view of the instant amendment to claims 22-24 and 30.

[7] The objection to claims 22-24 and 30 to in the recitation of "as part of the host cell chromosome,...extra-chromosomally to form the fusion protein...of a cell culture" is withdrawn in view of the instant amendment to claims 22-24 and 30.

[8] The objection to claim 23 as reciting a first method step, *i.e.*, "expressing the nucleic acid", yet the remaining method steps, *i.e.*, "separating", "culturing", etc., are denoted as (A), (B), etc. is withdrawn in view of the instant amendment to claim 23.

[9] The objection to claim 31 in the recitation of "R is an arginine codon or a chemical bond" is withdrawn in view of the instant amendment to claim 31.

[10] The objection to claim 32 under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim is withdrawn in view of the instant amendment to claim 32.

[11] The objection to claims 31-33 in the recitation of "(AsmR), taken together, is an arginine codon", "(AsmR), taken together, encodes", and "(AsmR), taken together, is either", respectively, is withdrawn in view of the instant amendment to claims 31-33.

[12] The objection to claim 33 in the recitation of "Sx is an a factor" is withdrawn in view of the instant amendment to claim 33.

[13] The objection to claim 35 in the recitation of "lepirudin which has been prepared recombinantly" is withdrawn in view of the instant amendment to claim 35.

[14] Claim 23 has been amended to change steps (B) and (C) to (C) and (D), respectively. Claim 23 is newly objected to in the recitation of "(E) repeating (B) and (C) several times" and in the interest of improving claim form, it is suggested that the phrase "(E) repeating (B) and (C) several times" be amended to recite, *e.g.*, "(E) repeating (C) and (D) several times".

Claim Rejections - 35 USC § 112, Second Paragraph

[15] The rejection of claims 22-24 and 30 under 35 U.S.C. 112, second paragraph, as lacking antecedent basis in the recitation of "...the nucleic acid of a host cell..." in the phrase "expressing the nucleic acid of a host cell comprising: a nucleic acid sequence comprising:" is withdrawn in view of the instant amendment to claims 22-24 and 30 to replace the phrase "expressing the nucleic acid of a host cell comprising: a nucleic acid

sequence comprising:" with "culturing a host cell comprising a nucleic acid, the nucleic acid comprising:".

[16] The rejection of claims 32-33 under 35 U.S.C. 112, second paragraph, as being confusing in the recitation of "(AsmR)...encodes SEQ ID NO:12 (Gly-Asn-Ser-Ala-Arg)" and "(AsmR)...encodes SEQ ID NO:12", respectively is withdrawn in view of the instant amendment to claim 31 to recite "(AsmR) is an arginine codon or encodes SEQ ID NO:12".

Claim Rejections – Double Patenting

[17] The rejection of claims 22-24, 30-31, and 35 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2, 11-12, 15, and 17 of US Patent 7,202,059 B2 in view of Dörschug et al. (US Patent 6,875,589) and Schmid et al. (US Patent 5,919,895) is maintained for the reasons of record and the reasons set forth below. The rejection was fully explained in the prior Office action. See [17] beginning at p. 5 of the Office action mailed on 1/15/10.

[18] The rejection of claim 32 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 2 of US Patent 7,202,059 B2 in view of Dörschug and Schmid is maintained for the reasons of record and the reasons set forth below. The rejection was fully explained in the prior Office action. See [18] beginning at p. 8 of the Office action mailed on 1/15/10.

[19] The rejection of claims 31 and 35 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of US Patent 7,638,618 B2 is maintained for the reasons of record and the reasons set forth below. The rejection was fully explained in the prior Office action. See [19] beginning at p. 9 of the Office action mailed on 1/15/10.

[20] The rejection of claims 22-24 and 30 are newly rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 4 and 7-8 of US Patent 7,638,618 B2 in view of Dörschug et al. (US Patent 6,875,589) is maintained for the reasons of record and the reasons set forth below. The rejection was fully explained in the prior Office action. See [20] beginning at p. 10 of the Office action mailed on 1/15/10.

[21] The rejection of claim 33 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of US Patent 7,638,618 B2 is maintained for the reasons of record and the reasons set forth below. The rejection was fully explained in the prior Office action. See [21] beginning at p. 11 of the Office action mailed on 1/15/10.

RESPONSE TO ARGUMENT: Beginning at p. 7 of the remarks filed on 6/21/10, applicant requests the rejections be deferred until an indication of allowable subject

matter. The rejections are maintained for the reasons of record. It is noted that aside from objections and the instant obviousness-type double patenting rejections, there are no other pending rejections.

Conclusion

[22] Status of the claims:

- Claims 22-24, 30-33, and 35 are pending.
- Claims 22-24, 30-33, and 35 are rejected.
- No claim is in condition for allowance.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Steadman whose telephone number is 571-272-0942. The examiner can normally be reached on Mon to Fri, 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/David J. Steadman/
Primary Examiner, Art Unit 1656